

### **REMARKS**

In accordance with the Examiner's request, new paragraphs have been added to the specification to describe Figs. 31 and 32.

Applicants respectfully request that the United States Patent & Trademark Office (USPTO) withdraw its' double patenting rejection based upon US Patent No. 6,613,062 issued to Leckrone. Applicants respectfully assert that the claimed invention is patentable distinct from claims 1-19 of Leckrone. For example, Leckrone does not have independent claims that include a locking mechanism. The locking mechanism of the claimed invention relates to "the inwardly directed projections of the outer tubular body and the outwardly directed projections of the inner tubular member, wherein in a first rotational position of the inner tubular member relative to the outer tubular body, the inwardly and outwardly directed projections and the defined recesses permit the inner tubular member to longitudinally move within the lumen of the outer tubular body and, in a second rotational position of the inner tubular member relative to the outer tubular body, the inwardly and outwardly directed projections are caused to engage one another in an interlocking relationship to prevent longitudinal movement of the inner tubular member within the lumen of the outer tubular body." Co-pending applications 10/606,908, 11/000,538, and 11/000,539 also lack a similar locking mechanism. For at least this reason, the claimed invention is patentably distinct from Leckrone and the co-pending applications.

Claims 39-41 and 43-45 remain pending and under consideration.

In the March 1, 2006, office action, a new ground of rejection was made. As to Claims 39, 41, and 43-45 now stand rejected as being unpatentable over Bonutti (US 6,187,023) in view of Suzuki et al. (US 4, 682,981). There was no specified rejection of claim 40. However, Applicants assume that the examiner intended to include claim 40 in the rejection.

Bonutti discloses a fluid operated retractor to retract tissue. The structure shown in Fig. 13 is of a pair of the retractors that are used together such that

there is an inner bladder 160 and an outer bladder. Inflation of the two bladders pulls the tissue away from the joint.

First, Bonutti is completely without relevance to a fluid delivery apparatus. The contention that it would have been obvious to use Bonutti's apparatus in combination with a cannula for fluid delivery is completely without support. Nowhere is there any identification of a suggestion or motivation to provide the structure disclosed in Bonutti with a fluid delivery catheter as set forth in claims 39 and 40. For a valid obviousness rejection, there must be a suggestion from among the references themselves to make the claimed combination. The rejection is in error on this fundamental point and should be withdrawn.

Further, Bonutti is acknowledged to be without a locking mechanism. Thus, Suzuki is being relied upon for that limitation. Suzuki discloses a device having a sheath portion 2 (Fig. 2) and a dilator portion 3 (Fig. 4). These two components are taper-fitted to form an interference fit that resists both rotational and axial relative movement that would separate them apart. Also provided are grooves 9 in the sheath portion 2 (See Figs. 2 and 3) and mating ribs 12 (See Fig. 4). The grooves form a series of keyways and the ribs (splines) form keys that fit into the keyways. Furthermore, the grooves 9 are on the outer portion of the device and the ribs are on the inner portion of the device. Upon insertion of dilator portion 3 into sheath portion 2, an interlocking of the ribs and grooves is established.

The structure in Suzuki is not in conformance with the recitation in claim 39 and does not meet the locking mechanism limitation of claim 39.

The specific limitation in claim 39 is as follows:

a locking mechanism comprising the inwardly directed projections of the outer tubular body and the outwardly directed projections of the inner tubular member, wherein in *a first rotational position of the inner tubular member relative to the outer tubular body*, the inwardly and outwardly directed projections and the defined recesses permit the inner tubular member to longitudinally move within the lumen of the outer tubular body and, in *a second rotational position of the inner tubular member relative to the outer tubular*

*body, the inwardly and outwardly directed projections are caused to engage one another in an interlocking relationship to prevent longitudinal movement of the inner tubular member within the lumen of the outer tubular body*

The locking mechanism of claim 39 is clearly specified to require relative rotational movement between the inner and outer tubular members so that relative longitudinal movement is prevented. Thus, Suzuki is inapposite to the recited locking mechanism. That is, whereas the structure recited in claim 39 allows relative rotational movement between the interlocking pieces into a position that prevents relative longitudinal movement, Suzuki allows relative longitudinal movement between the interlocking pieces into a position that prevents relative rotational movement.

Accordingly, combining Suzuki with Buonetti fails to result in the claimed subject matter as a whole. Necessarily, the rejection of claims 39, 41 and 43-45 fails as well and should be withdrawn.

As to claim 40, Applicants have elected to invoke Section 112, paragraph 6, in reciting a means-plus-function limitation of "means adjacent the distal end of the tubular member for stabilizing the tubular member relative to body tissue through which the tubular member may extend." In accordance with the provisions of Section 112, paragraph 6, the limitation is construed as covering the corresponding structure linked in the specification for performing the specified function, as well as equivalent structures. The function is "stabilizing the tubular member relative to body tissue through which the tubular member may extend." The structure linked in the specification to this function is identified in paragraphs [58] and [61] and includes flanges 216/218 (Fig.9) and the interlocking projections (Figs. 10 and 11).

Absent from both Bonutti and Zuzuki is any structure performing the function of "stabilizing" the tubular member relative to body tissue through which the tubular member may extend. The function of the structure shown in Fig. 13 of Bonutti, as clearly stated in column 10, lines 7-23, is that of retraction of tissue to create a working space. Furthermore, Bonutti is admitted to be without any

locking mechanism for the bladders. Yet further, neither Bonutti nor Zucki discloses the structure of flanges 216/218 (Fig.9) and the interlocking projections (Figs. 10 and 11). The interlocking projections require relative rotational movement between them so that stabilization of the tubular member relative to the tissue is realized. The interlocking projections allow relative rotational movement between the interlocking pieces into a position that prevents relative longitudinal movement. In contrast, Suzuki allows relative longitudinal movement between the interlocking pieces into a position that prevents relative rotational movement. Thus, the structure in Suzuki is neither identical nor equivalent to the interlocking projections shown in Figs. 10 and 11 and described in paragraphs [58] and [61].

Accordingly, combining Suzuki with Buonetti fails to result in the claimed subject matter as a whole. Necessarily, the rejection of claim 40 fails as well and should be withdrawn.

The USPTO rejected claims 39, 41, 43-45 for double patenting. Applicants will file a terminal disclaimer for the listed patent applications with serial numbers 10/606,908, 11/000,538, 11/000,539 provided the patent application becomes an issued patent and the double patenting rejection applies. With respect to U.S. Patent No. 6,613,062, Applicants respectfully disagree that the referenced claims involve double patenting. For example, the independent claims in U.S. Patent No. 6,613,062 do not expressly disclose a "locking mechanism." For at least this difference, Applicants respectfully request withdrawal of the double patenting rejection.

### **III. Conclusion**

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

Finally, if there are any formal matters remaining after this Amendment, the Examiner is requested to telephone the undersigned attorney to attend to those matters.

Respectfully submitted,

MICHAEL E. LECKRONE ET AL.

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Date

/Carol F. Barry/  
Carol F. Barry  
Reg. No. 41,600  
(763) 514-4673  
Customer No. 27581